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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/430,590	10/29/99	POULTER R	674521-2001.

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EXAMINER	
JEFFERS JR.G	
ART UNIT	**PAPER NUMBER**
1636	24

DATE MAILED: 09/13/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

1- File Copy

PTO-90C (Rev. 2/95)

Office Action Summary	Application No. 09/430,590	Applicant(s) POULTER ET AL.	
	Examiner Gerald Leffers	Art Unit 1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 August 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-32* is/are pending in the application.

4a) Of the above claim(s) *7,8,15,16 and 22-32* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,9-14 and 17-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Yvonne Adams

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Receipt is acknowledged of a new paper copy of the sequence listing, corresponding CRF and attorney's statement. Applicants are hereby notified that the CRF of the sequence listing has been modified by STIC as follows: an authorized insertion of <220> to <223> information for SEQ ID NO: 150.

Election/Restrictions

Applicants' election with traverse of Group I (claims 1-6, 9-14, 17-21 in Paper No. 23 (filed 8/15/01) is acknowledged. The traversal is on several grounds that are summarized as follows: 1) applicants request consideration of SEQ ID NOS: 113, 114 and 115 which are directed towards a C. albicans Tca3 retrotransposon 14, 2) a search of the sequence of a retrotransposon and its corresponding protein would encompass the sequence of other similar retrotransposons, 3) there would not be a serious search burden for the examiner to search the different groups, 4) the different claims all "comply" with group I, 5) each of the claims is tied together by a single inventive concept and have unity of invention, 6) the methods claims are tied to the product claims and must be searched and examined together in the application (M.P.E.P. §821.04), and 7) all of the claims are ultimately directed towards a novel retrotransposon, pCal, which belongs to the Tyl/copia group of retrotransposons. These arguments are not found persuasive because of the following reasons.

Applicants' assertion that each of the claims is directed towards the retrotransposon pCal is not accurate. As stated in the restriction requirement, Groups 2-79 are each directed towards a retrotransposon which is chemically, structurally and operationally distinct from the pCal

retrotransposon of Group 1. As such, each nucleic acid sequence encoding one of the putative retrotransposons of Groups 2-79 requires a separate patent and non-patent literature search. Applicants' argument that a search of the retrotransposon of Group 1 would necessarily "encompass" the nucleic acids of the retrotransposons of the other groups is inaccurate. While these putative retrotransposon sequences were identified based on some degree of similarity to the retrotransposon of Group 1, the "similarity" is not exactly co-extensive to the sequence of the pCal retrotransposon. Therefore, a separate search is required for each putative retrotransposon. This is all that is required to demonstrate a burdensome search. Applicants have not demonstrated why the sequences encoding the Tca3 retrotransposon (SEQ ID NOS: 113, 114 and 115) should be included with the retrotransposon of Group 1, which is sequentially, structurally and operationally distinct from the Tca3 retrotransposon represented by these sequences

Applicants' arguments with regard to "single inventive concept" or "unity of invention" are more properly directed towards an application filed under the PCT. These arguments are not relevant towards this case, which has been filed under 35 U.S.C. 111.

Finally, applicants' response has mischaracterized M.P.E.P. §821.04. This section of the M.P.E.P. states:

> Where product and process claims drawn to independent and distinct inventions are presented in the same application, applicant may be called upon under 35 U.S.C. 121 to elect claims to either the product or process. See MPEP § 806.05(f) and § 806.05(h). The claims to the nonelected invention will be withdrawn from further consideration under 37 CFR 1.142. See MPEP § 809.02(c) and § 821 through § 821.03. However, if applicant elects claims directed to the product, and a product claim is **subsequently found allowable**, withdrawn process claims which depend from or otherwise include all the limitations of the allowable product claim will be rejoined. (examiner's emphasis added)

Upon an indication of allowable subject matter for the elected product claims, rejoinder of methods claims dependent upon, or otherwise including all the limitations of, any allowable product claim will be considered.

The requirement is still deemed proper and is therefore made FINAL. Claims 1-32 are pending in this application, with claims 7-8, 15-16, and 22-32 are withdrawn from consideration as being drawn towards nonelected inventions.

Drawings

This application has been filed with informal drawings which are acceptable for examination purposes only. Formal drawings will be required when the application is allowed.

Color photographs and color drawings are acceptable only for examination purposes unless a petition filed under 37 CFR 1.84(a)(2) or (b)(2) is granted permitting their use as formal drawings. In the event applicant wishes to use the drawings currently on file as formal drawings, a petition must be filed for acceptance of the photographs or color drawings as formal drawings. Any such petition must be accompanied by the appropriate fee as set forth in 37 CFR 1.17(i), three sets of drawings or photographs, as appropriate, and an amendment to the first paragraph of the brief description of the drawings section of the specification which states:

> The file of this patent contains at least one drawing executed in color. Copies of this patent with color drawing(s) will be provided by the Patent and Trademark Office upon request and payment of the necessary fee.

Color photographs will be accepted if the conditions for accepting color drawings have been satisfied.

Specification

The disclosure is objected to because of the following informalities: drawings are present in the specification which would be more properly placed in the drawings section of the specification (e.g. see the drawings on pages 81-86).

The disclosure is also objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See M.P.E.P. §608.1.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-6 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1-6 are each drawn towards an isolated retrotransposon having a copy number of "between 40-150 or 50-100 copies" of itself per genome. The retrotransposon can be "free" or episomal, or the retrotransposon can be integrated. The retrotransposon can be isolated from fungi or yeast, or more specifically from Candida albicans. The broadest embodiments

potentially encompass literally any eukaryotic cell type which might harbor a retrotransposable element (e.g. corn, yeast, human, fly, etc.). Even in more specific embodiments, the claims encompass any strain of Candida or, more specifically, Candida albicans. Each of the claims comprises the functional limitation of between 40 and 150 copies of itself per host cell genome.

The specification teaches one embodiment of the claimed invention (pCal or Tca2) which is found at high copy number in a few particular strains of C. albicans. No definitive explanation is provided in the specification for why pCal is maintained at such high copy number in these particular strains of C. albicans and not in others. For example, the mechanism could involve some mutation in pCal or a mutation in the particular host, or a combination of mutations in both the host and pCal. The prior art is of no help in describing a mechanistic rational for maintenance of such high copy numbers because the art does not appear to teach such numbers.

Given the large number of host cell types and retrotransposable elements potentially embraced by the rejected claims and the presence of the functional limitation for high copy number, the presence of only a single relevant example in the specification or prior art meeting the functional limitation for high copy number and the lack of teachings from the specification or prior art as to how such a high copy number is attained by the single relevant example, one of skill in the art would not be able to envision a representative number of specific embodiments of the claimed invention to describe the potentially broad genus of such retrotransposable elements embraced by the rejected claims. Therefore, one of skill in the art would reasonably conclude applicants were not in possession of the claimed invention at the time of filing.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-6, 9-14, 17-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague and indefinite in that the metes and bounds of the phrase "..having a copy number of between 40-150 or 50-100 copies of free DNA of itself per genome.." are unclear. The presence of two different and overlapping ranges of copy numbers for the recited retrotransposon in the same claim makes it unclear as to which range is relevant. Also, it is unclear what exactly is meant by the term "free copies of itself". Upon reading the specification it appears that the term is meant to encompass episomal, DNA copies of a retroviral sequence. Does this mean that the "free copies" are autosomal or that they are merely intermediates in a replication/integration pathway? It is further unclear as to how the non-integrated retrotransposon of the invention can be present in or "per genome". Finally, it is unclear as to which genome the copy number is to be compared. It would be remedial to amend the claim language to include a single range of copy numbers for the claimed retrotransposon and to more clearly indicate the limitations intended by the cited phrase.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by

raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 4 recites the broad recitation "from fungi or yeast", and the claim also recites "including Candida or Candida albicans" which are the narrower statements of the range/limitation.

Claim 5 is vague and indefinite in that the metes and bounds of the term "...capable of integrating into the DNA in a genome providing a copy number of between 40-150 or 50-100 copies per genome..." are unclear. As noted above for claim 1, the presence of two ranges for the copy number of the retrotransposon makes the claim indefinite. Further, it is unclear as the claim is written under what conditions the retrotransposon is "capable of" integrating into the genome of a host to produce the high copy number recited in the claim language (e.g. which host is considered to be the standard for determining the limitation?). Finally, it appears from the specification that the large number of copies are of the retrotransposon are intended to be episomal. It appears from the claim language that the recited number of copies may necessarily be integrated into the genome of the host cell. It would be remedial to amend the claim language to specify a single range for the copy number, to clearly indicate the conditions under which the retrotransposon integrates and produces the recited copy number and to clearly indicate whether the recited number of copies are integrated into the host genome or are episomal.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim

does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 6 recites the broad recitation "fungi or yeast", and the claim also recites "Candida albicans" which is the narrower statement of the range/limitation.

Claims 9-10 are vague and indefinite in that the metes and bounds of the phrase "...comprising an internal domain for receiving a nucleotide sequence encoding a desired protein flanked by two long terminal repeat regions having the sequence identified in Figure 2B..." are unclear. The terms "internal domain for receiving a nucleotide sequence" and "long terminal repeat regions" have not been clearly defined in the specification. What exactly constitutes a "domain" for "receipt" of a nucleotide sequence? Does the term refer to a restriction endonuclease site or sites? Does the term long terminal repeat "region" refer to particular nucleotides within the sequence shown in Figure 2B, and if so, which ones? It would be remedial to amend the claim language to more clearly indicate the limitations intended by the terms "internal domain for receiving a nucleotide sequence" and "long terminal repeat regions".

Claims 10 and 18 are vague and indefinite in that the metes and bounds of the term "system" are unclear. The term "system" followed by the open term "comprising" implies a combination of both methods and products designed to accomplish the end result of a method, thus making it unclear as to the nature of what is being claimed. It would be remedial to amend the claim language to more clearly indicate whether the claim is directed towards a method or towards a product.

Claims 12 and 19 are vague and indefinite in that the metes and bounds of the phrases "…with the LTR and POL region of Figure 2B…", "…hybridizes under conditions of standard stringency…" and "…A functional fragment…" are unclear. The LTR and POL regions are not explicitly defined in Figure 2B as to their boundaries. It would be remedial to amend the claim language to explicitly list nucleotide boundaries for the LTR and POL "regions". What exactly are "standard" hybridization conditions? What exactly would constitute a "functional fragment" of any one of the other sequences recited in the claim? Which function is specified? Hybridization to another nucleic acid? Encoding a retrotransposon polypeptide? Anti-sense? It would be remedial to amend the claim language to more clearly indicate what is intended by the cited terms.

Claim 17 is vague and indefinite in that the metes and bounds of the term "retroviral-like carrier system" are unclear. In what manner and to what degree is the claimed product/method "retroviral-like"? As indicated above, the term "system" followed by the open-language term "comprising" implies a combination of methods steps and product compositions. It would be remedial to amend the claim language to more clearly indicate what is intended by the terms "retroviral-like" and "system".

Claim 21 is vague and indefinite in that the metes and bounds of the phrase "...particularly as seen in Figure 2B..." are unclear. Does the term "particularly" implies that the correspondence to the sequences given in Figure 2B is optional? Also, in what way do the recited genes correspond to Figure 2B? Is the correspondence at the level of nucleotide sequence or at the level of gene order? It would be remedial to amend the claim language to more clearly indicate in what manner the claimed nucleic acid fragment corresponds to the retrotransposon sequence described in Figure 2B.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-6, 9-14 and 17-21 are rejected under 35 U.S.C. 102(a) as being anticipated by Mathews et al (J. Bactiol. 1997, Vol. 179, pages 7118-7128; see the entire reference).

Mathews et al teach the isolation and characterization of the retroviral element of the instant invention, pCal, from the yeast Candida albicans (e.g. Abstract, Figure 2). It is noted that the authors of the Mathews et al reference are different from the inventorship of the instant application. Therefore, the Mathews et al reference constitutes work by "others".

Claim 5 is rejected under 35 U.S.C. 102(b) as being anticipated by Farman et al (Mol. Gen. Genet. 1996, Vol. 251, pages 665-674; see the entire document).

Farmen et al teach the isolation and characterization of a retrotransposable element from the rice blast fungus Magnaporthe grisea, MAGGY, which can be found at more than 50 copies in a particular isolate (AR4) (e.g. Abstract; page 670, paragraph 3).

Conclusion

No claims are allowed.

Certain papers related to this application may be submitted to Art Unit 1636 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. §1.6(d)). The official fax telephone numbers for the Group are (703) 308-4242 and (703) 305-3014. NOTE: If applicant does submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gerald Leffers , Jr. whose telephone number is (703) 308-6232. The examiner can normally be reached on Monday through Friday, from about 9:00 AM to about 5:30 PM. A phone message left at this number will be responded to as soon as possible (usually no later than 24 hours after receipt by the examiner).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's acting supervisor, Rob Schwartzman, Ph.D., can be reached at (703) 308-7307.

Any inquiry of a general nature or relating to the status of this application, or relating to attachments to this office action, should be directed to the Patent Analyst Zeta Adams, whose telephone number is (703) 305-3291.

GLJr

G. Leffers Jr., Ph.D.
Patent Examiner
Art Unit 1636
September 10, 2001

DAVID GUZO
PRIMARY EXAMINER